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| 10/583,233 | 01/17/2008 | Karen Elizabeth Barrett | T3106(C) | 8248 |

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| EXAMINER | |
|---|---|
| DAVIS, DEBORAH A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 02/02/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentgroupus@unilever.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/583,233 | BARRETT ET AL. | |
| | Examiner | Art Unit | |
| | DEBORAH A. DAVIS | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *4-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) *8-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7,16,18 and 19* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Supplemental Office Action*

This supplemental Office action was necessitated by a request from the applicant to correct the shortened statutory period of reply from 1 month to 3 months. Please refer to the previous Office action with respect all other information including the cited PTO-892 references therein.

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 September 2010 has been entered. Currently, claims 4-16, and 18-19 are pending. Claims 8-15 are withdrawn and 18-19 are newly added.

### *Claim Objections*

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claim 18 is drawn to a method of treating neuroendocrine-mediated psychologically induced stress by the administration of the composition as recited therein. Claim 19 does not further

limit the claimed method because it is drawn to an in-vitro assay that comprise contacting steps involving testing of derma cells and analyzing one or more markers.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors regarding undue experimentation have been summarized in In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The State of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

**Nature of the invention**: The claims are drawn to a method capable of inhibiting neuroendocrine-mediated psychologically induced stress on the skin of a human or animal which comprises administering to the individual a composition capable of inhibiting glucocorticoid-induced chronic stress in a dermal cell or a cell involved in skin inflammatory responses said method including preparing the composition by incorporation therein, a first substance selected from the group consisting of ginseng Rb1, ginseng Rc, curcumin, 22-OH-cholesterol, ciglitazone, mevinolin, commipheric acid, okadaic acid, licorice extract and mixtures thereof; and a second substance selected from the group consisting of wolfberry extract, shiitake extract, activin, ginseng Rb1, ginseng Rc, curcumin, ciglitazone, commipheric acid, boswellia extract and mixtures thereof, provided that said first substance and second substance are different. Wherein the composition inhibits glucocorticoid-induced chronic stress in an in-vitro assay comprising the steps of: contacting a dermal cell or a cell involved in skin inflammatory responses with the composition in the presence of a glucocorticoid receptor agonist under conditions and for a period of time that would, in the absence of the candidate first and second substance, lead to the cell being chronically stressed; subjecting the cell to acute stress; analyzing one or more cellular markers selected from a marker of inflammatory cell recruitment, where the cell is a cell involved in skin inflammatory responses; a marker of matrix degradation, where the cell is a dermal cell; and/or a marker of matrix synthesis in the cell, where the cell is a dermal cell;

determining whether the composition affects the status of the one or more cellular marker.

**Breadth of the claims:** The claims were given its broadest and reasonable interpretation that is consistent with applicant's specification description of the claimed method.

**Guidance of the Specification and Existence of Working Examples:**

The specification describes the method of claim 4 as two separate methods. The first method in the specification describes in a third aspect of the present invention a method for identifying a compound capable of reducing the effects of psychologically-mediated stress on the skin of a human or animal, which comprises contacting a dermal cell or a cell involved in skin inflammatory responses with the composition in the presence of a glucocorticoid receptor agonist under conditions and for a period of time that would, in the absence of the candidate first and second substance, lead to the cell being chronically stressed; subjecting the cell to acute stress; analyzing one or more cellular markers selected from a marker of inflammatory cell recruitment, where the cell is a cell involved in skin inflammatory responses; a marker of matrix degradation, where the cell is a dermal cell; and/or a marker of matrix synthesis in the cell, where the cell is a dermal cell; determining whether the composition affects the status of the one or more cellular marker (see, e.g., specification, page 3, lines 22-32 through page 4, lines 1-5). The second method of the claims described in the specification comprises a method of administering to the individual a composition capable of inhibiting glucocorticoid-induced chronic stress in a dermal cell or a cell involved in skin inflammatory responses said

method including preparing the composition by incorporation therein, a first substance selected from the group consisting of ginseng Rb1, ginseng Rc, curcumin, 22-OH-cholesterol, ciglitazone, mevinolin, commipheric acid, okadaic acid, licorice extract and mixtures thereof; and a second substance selected from the group consisting of wolfberry extract, shiitake extract, activin, ginseng Rb1, ginseng Rc, curcumin, ciglitazone, commipheric acid, boswellia extract and mixtures thereof, provided that said first substance and substance are different. The two methods described above are clearly described in the instant specification as separate methods. There are not working example of a single embodiment in the specification describing claim 4 as a single method of administering the disclosed composition and using the administered composition in an in-vitro assay. Although the M.P.E.P. does not require working examples, there must be at least sufficient teaching to enable one of ordinary skill in the art to practice the method without undue experimentation.

The office does not have the facilities for examining and comparing applicant's claimed method with the separate distinct methods of the prior art in order to establish that the method of the prior art can be practiced in one combined single method. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed method is one process. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

**Predictability and State of the Art:** The state of the art at the time the invention was made was unpredictable. There is no prior art that describes the combined methods of claim 4. For example, the reference of Leonard Buckbinder (US

2003/0224349) teaches a general in-vitro assay for identifying glucocorticoid compounds. The reference of Majeed et al. that is cited below teaches a composition comprising the ingredients required by the instant claim 4 which has anti-aging and UV protective properties. There is nothing in the prior art or in the instant specification that teach or suggest that the method disclosed in claim 4 can be a single combined method. Thus, it is clear that the method of the instant claim 4 comprise of two separate methods.

Therefore, in view of the breadth of the claims and the lack of guidance in the specification as well as the unpredictability of the art, it would have required an undue amount of experimentation to administer the cited composition to a mammal and take the same composition administered to the mammal and use it in an in-vitro assay in a single method. Therefore the instant clams are not considered to be enabled by the instant specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over rejected over Majeed et al. (US 2004/0121031).

The claims are drawn to a method of reducing the effects of neuroendocrine-mediated psychologically-induced stress on the skin of a human desiring to reduce psychologically-induced stress on their skin, said method comprising administering to said human a composition comprising a first substance selected from the group consisting of ginsenoside Rb1, ginsenoside Rc, curcumin, 22-OH-cholesterol, ciglitazone, mevinolin, commipheric acid, okadaic acid, licorice extract and mixtures thereof; and a second substance selected from the group consisting of wolfberry extract, shiitake extract, activin, ginseng Rb1, ginseng Rc, curcumin, ciglitazone, commipheric acid, boswellia extract and mixtures thereof, provided that said first substance and second substance are different.

The reference of Majeed et al. beneficially teaches a topical skin composition comprising glabridin or extracts thereof (i.e. licorice) that also may include curcumin as a tyrosine inhibitor. The glabridin extract is useful as an anti-wrinkle and anti-aging, providing elasticity, firminess, tone and texture to the skin, ameliorating fine lines and preventing skin damage due to UV rays, and prevent skin damage induced by inflammation. It is known that UV ray damage exposure can be induced stress on the skin. The fist and second substances in the composition (i.e. glabrindin and curcumin) are different, as required by the instant claims. The composition can be administered orally or topically (see e.g., abstract, paragraphs 0003, 0006, 0019, 0021, 0046-0047). Applicant has defined the term “neuroendocrine-mediated psychologically-induced stress” on the skin would encompass stress on the skin resulting from everyday life (see e.g., specification page 1). Therefore the cited reference reads on the subject matter of

the instant claims because the composition is useful in protecting skin from daily stresses that can damage the skin which includes UV rays. Further, every human would desire to reduce the effects of stress on the skin to prevent damage thereof.

The reference of Majeed et al. does not expressly teach the active step of administering the composition to an individual.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the cited composition to an individual based on the protective properties of the skin that include anti-aging, UV protection and overall skin tone.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments filed 9-21-10 have been fully considered but they are not persuasive.

Applicant has amended the claims and has presented arguments against the current rejection of Shefer et al. over claims 4-7, and 16. However, these arguments are considered to be moot in view of applicant's amendments to the claims and the newly applied rejection. Also, the current reference of Shefer et al. do not read on the

claims as amended and is therefore withdrawn. The examiner has also considered the reference of Shefer et al. against the new claim 18, but has decided to apply the reference of Majeed et al. that better reflects applicant's invention.

All other objections and rejections are hereby withdrawn.

## *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 2011

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